RATIONALE FOR THE DEVELOPMENT OF ONTARIO AIR STANDARDS FOR 1,4-DICHLOROBENZENE

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Executive Summary

The Ontario Ministry of the Environment has identified the need to develop and/or update air quality standards for priority contaminants. The Ministry's Standards Plan, which was released in October 1996, identified candidate substances for the development of air standards for the next several years (MOEE, 1996). 1,4-Dichlorobenzene (1,4-DCB) was identified as a priority for review based on its identification as a priority contaminant under the Canada-Ontario Agreement and the fact that Ontario does not currently have an air quality standard for this substance.

1,4-Dichlorobenzene or para-dichlorobenzene is a white, crystalline substance of low water solubility with a penetrating odour. In Canada it is used as a deodorizer in public facilities, in pesticide formulations, as a fumigant for control of mildew and moulds, and in moth and bird control products. It also has a number of uses in various industrial processes. Mean airborne 1,4-dichlorobenzene levels at a number of stations throughout Canada ranged from 0.22 to 2.94 $\mu g/m^3$ (micrograms per cubic metre), with an overall mean of 0.92 $\mu g/m^3$. The maximum (24-hour) average levels were measured in the industrial sections of Vancouver, Toronto and Windsor and reported as 4.82, 15.7 and 14.6 $\mu g/m^3$, respectively.

The physiological response to 1,4-dichlorobenzene is primarily injury to the liver, and secondarily, injury to the kidney. Information is considered to be inadequate to make a decision regarding its human carcinogenicity. Experimental studies on carcinogenicity in animals suggest that 1,4-dichlorobenzene may be potentially carcinogenic but the information is still too limited to derive any firm conclusions. Health Canada classifies 1,4-dichlorobenzene as a Group III carcinogen (possibly carcinogenic to humans).

Ontario does not currently have air quality standards for 1,4-dichlorobenzene. In developing air quality standards for Ontario, the Ministry of the Environment is reviewing and considering air quality guidelines and standards used by leading agencies worldwide. Of the criteria reviewed from other agencies, the Tolerable Concentration of 95 $\mu g/m^3$ for 1,4-dichlorobenzene developed by Health Canada under the Canadian Environmental Protection Act, was judged to have the most appropriate rationale. This value is based on long-term inhalation studies with experimental animals in which increases in liver and kidney weights and urinary protein were observed (CEPA, 1993).

Based on an assessment of ambient air quality guidelines used in other jurisdictions; the toxicity of this compound and the levels of 1,4-dichlorobenzene measured in Ontario, the Ministry is proposing to establish:

- a 24-hour average Ambient Air Quality Criterion for 1,4-dichlorobenzene of 95 $\mu g/m^3$ (micrograms dichlorobenzene per cubic metre of air);

- a half-hour Point of impingement guideline of 285 µg/m^3. The point of impingement guideline is based on the proposed 24-hour Ambient Air Quality Criterion and will be used to review and assess applications for Certificates of Approval involving emissions of 1,4-dichlorobenzene from new or modified sources.

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1.0 Introduction

Ontario's primary approach to regulating air emissions is based on achieving and maintaining air quality which is protective of human health and the environment. The *Environmental Protection Act* requires all stationary sources which emit or have the potential to emit a contaminant to obtain a Certificate of Approval which outlines the conditions under which the facility can operate.

Compliance with air quality standards and guidelines is one of the criteria used to issue Certificates of Approval. Sources or potential sources of a contaminant are required to control emissions to ensure that the concentration of a contaminant specified by the standard is not exceeded at any point off their property. Dispersion modelling which incorporates detailed engineering calculations is used to relate emission rates from a source to resulting ambient concentrations of a particular contaminant.

The Ministry of the Environment uses a combination of regulatory standards, ambient air quality criteria (AAQCs) and point of impingement (POI) guidelines in reviewing Certificates of Approval (MOEE, 1994a). Point of impingement standards are established under Regulation 346 and can be used directly as enforcement tools as the regulation specifies that a source cannot emit a contaminant at a level which would result in a standard being exceeded at its maximal point of impingement off its property (Section 5(3)). All sources are required to comply with Regulation 346 POI standards unless they are specifically exempted in regulation. As POI standards specified under Regulation 346 apply to all sources, socio-economic issues need to be taken into consideration in their development to ensure that the standards are technically feasible and there is a balance between the benefits and costs of improved ambient air quality.

In addition to POI standards established under Regulation 346, the Ministry also has a larger number of ambient air quality criteria and point of impingement guidelines which are derived from AAQCs. These are used by the Ministry to assess general air quality and the *potential* for causing an adverse effect (MOEE 1994). Like POI standards specified in Regulation 346, point of impingement guidelines are also used in Certificates of Approval to approve new and modified emission sources. Once incorporated into a legal instrument like a Certificate of Approval, point of impingement guidelines are legally binding, however unlike Regulation 346 POI standards, they do not automatically apply to existing sources at the time they are promulgated. AAQCs are normally set at a level not expected to cause adverse human health or environmental effects based on continuous exposure. As such, socio-economic factors such as technical feasibility and costs are not explicitly considered when establishing such limits.

Generally, point of impingement standards and guidelines which employ half-hour averaging times are set such that compliance with the standard or guideline will ensure that the Ambient Air Quality Criterion which is based on longer term averaging periods (e.g. 24-hours) will be met. In certain cases where the effect can occur over short-term exposures, like odours, the 24-hour

Ambient Air Quality Criterion and the half-hour point of impingement standard may have the same value.

The Ontario Ministry of the Environment has identified the need to develop and/or update air guidelines/standards for priority toxic contaminants. The Ministry's Standards Plan, which was released in October 1996, identified candidate substances for the development of air standards for the next several years. 1,4-Dichlorobenzene was identified as a priority for review based on its identification as a priority contaminant under the Canada-Ontario Agreement and the fact that Ontario does not currently have an air quality standard for this substance. This document provides the rationale for the establishment of an AAQC and point of impingement guideline for 1,4-dichlorobenzene.

2.0 Review and Evaluation

2.1 General Information

1,4-Dichlorobenzene, or para-dichlorobenzene ($C_6H_4Cl_2$), is a white, crystalline substance of low water solubility, with an odour described as penetrating and camphoraceous. The odour threshold is reported to be as low as 0.18 ppm (approximately 1.08 mg/m^3). The Chemical Abstracts Service (CAS) identification number is 106-46-7, the Registry of Toxic Effects of Chemical Substances (RTECS) number is CZ455 and the United Nations Hazardous Material number is UN1592. In Canada it is used as an air freshener, a deodorizer in urinals, in pesticides, as a fumigant for control of mildew and moulds, and in moth and bird control products. It also has a number of uses in various industrial processes.

Deposition of 1,4-dichlorobenzene to water directly from runoff and soil erosion has the potential to contribute to build up in aquatic sediments due to its persistence in that medium. 1,4-Dichlorobenzene has been identified as a Tier II substance for voluntary release reduction and virtual elimination under the Canada-Ontario Agreement Respecting the Great Lakes Basin Ecosystem due to sediment persistence and potential effects on aquatic biota as well as its potential carcinogenicity in humans.

The adverse effect of 1,4-dichlorobenzene is primarily injury to the liver, and secondarily, injury to the kidneys. Other effects reported from occupational exposures include neural disorders and adverse effects on the blood. In an animal study rats, guinea pigs, rabbits, mice and monkeys were exposed via inhalation at various concentrations between 96 and 798 ppm (600 to 4800 mg/m^3) for 28 weeks. Although not all species were tested at each exposure level employed, at the highest concentration, signs of response included mortality, tremors, weight loss, and liver and kidney changes (ACGIH, 1991).

According to the International Agency for Research on Cancer (IARC, 1987) and the Amercian Conference of Governmental and Industrial Hygienists (ACGIH 1991), there is only one report that suggests an association between exposure to dichlorobenzenes and leukemia in workers. In experimental animals, rats and mice exposed to 1,4-dichlorobenzene at doses up to 500 ppm for one year, were negative for tumour formation. In addition, only increased liver weights and elevated urinary coproporphyrin were observed after a recovery period of 19 weeks for the mice and 35 weeks for the rats. Exposure to mice and rats by gastric intubation was reported to cause renal tumours in male rats and liver tumours in male and female mice (ACGIH, 1991). IARC (1987) classifies 1,4-dichlorobenzene as a possible human carcinogen (Group 2B) based on inadequate evidence for human cancer and sufficient evidence for carcinogenicity to animals.

2.2 Sources and Levels

The sole producer of 1,4-dichlorobenzene in Canada has reported approximately 10 tonnes released at its Quebec facilities (1995 NPRI), mainly due to leaks during storage and handling procedures. The inventory developed under the Canada-Ontario Agreement (COA) estimates that the 1996 releases to air in Ontario from consumer products containing 1,4-dichlorobenzene is approximately 200,000 kg/yr (200 tonnes). In contrast, the quantity released industrial sources is considerably less. The COA inventory estimates that a total of 55 kg of 1,4-dichlorobenzene is released yearly from sewage sludge incineration and municipal solid waste incineration (COA Inventory of Tier I and Tier II Substances).

Mean airborne 1,4-dichlorobenzene levels at 23 stations throughout Canada between October 1988 and December 1990 ranged from 0.22 to 2.94 $\mu g/m^3$, with an overall mean of 0.92 $\mu g/m^3$. In Ontario, studies in downtown Windsor over the period 1988-92 averaged in the range of 0.18-3.27 $\mu g/m^3$ annually (Windsor, 1994). A downtown Toronto site averaged in the range of 1.65-3.40 $\mu g/m^3$ over the same period. In Sarnia, annual averages ranged from 0.04 to 1.20 $\mu g/m^3$ over the period 1992-96 with an overall mean of approximately 0.30 $\mu g/m^3$. Maximum 24-hour average levels have been reported in the industrial sections of Vancouver, Toronto and Windsor, with levels of 4.82, 15.7 and 14.6 $\mu g/m^3$ respectively (CEPA, 1993). A small number of indoor air samples were taken in a Toronto office building in 1990 and analyses showed an average of 2.6 $\mu g/m^3$ over a 6-7 hour period. The maximum level was 7.6 $\mu g/m^3$ (MOE, 1991).

Mean concentrations of 3.2 $\mu g/m^3$ were found near industrial areas in New Jersey and 0.26 to 0.66 $\mu g/m^3$ near residential areas in New Jersey in 1978. Mean concentrations of 0.26 to 0.46 $\mu g/m^3$ were detected in the ambient air of three New Jersey cities during July-August 1981. Mean concentrations of 0.12 $\mu g/m^3$ were detected in the ambient air of Portland, Oregon during 1984. The ambient air of central Tokyo was reported in 1975 to contain 2.7 to 4.2 $\mu g/m^3$, and the air in suburban Tokyo contained 1.5 to 2.4 $\mu g/m^3$ (HSDB, 1996).

2.3 Review of Existing Air Quality Regulations.
Agency-specific summaries concerning air quality guidelines for 1,4- dichlorobenzene are presented in the Appendix of this report. A brief summary is presented in Table 1.

3.1 Regulatory Approaches for 1,4-Dichlorobenzene

The development of ambient air standards and acceptable exposure limits for long term exposure to 1,4-dichlorobenzene in air is based on two approaches. One approach is for the protection of human health from effects such as injury to the liver and (possibly) kidneys. The other approach is based on the avoidance of carcinogenic activity in humans. The two approaches are examined separately.

3.1.1 Regulatory Approaches for 1,4-Dichlorobenzene Based on a Carcinogenicity Endpoint

The States of Massachusetts and California are the only jurisdictions which have developed air quality guidelines based on carcinogenicity as an endpoint. There is a limited database on which to conclude that 1,4-dichlorobenzene is an animal carcinogen and there is little evidence that this substance is a human carcinogen (IARC, 1987; ACGIH, 1991; CEPA, 1993). According to the State of Massachusetts, at the time their long-term standard was promulgated, the USEPA had developed, but not yet published, a carcinogenic unit risk for inhalation of $5.7*10^{-6}$ for 1,4-dichlorobenzene, based on the results of studies on rats and mice exposed orally. This was similar to the unit risk of $6.1*10^{-6}$ calculated independently by the State of Massachusetts. However, according to the USEPA (USEPA, 1997), the carcinogenic potential of 1,4-dichlorobenzene is under review, and an inhalation unit risk does not currently appear on their IRIS database. California has developed a unit risk of $1.1*10^{-5}$ tumours per $\mu g/m^3$ to be used for evaluation of cancer risks (CAPCOA, 1993). Under the Canadian Environmental Protection Act (CEPA), Health Canada and Environment Canada consider 1,4-dichlorobenzene to be possibly carcinogenic to humans (Group III). This classification is based on limited available information of carcinogenicity in animals and inadequate data to assess the 1,4-dichlorobenzene carcinogenicity in humans (CEPA, 1993).

3.0 Development of an Ambient Air Quality Criterion for Ontario

3.1.2 Regulatory Approaches for 1,4-Dichlorobenzene Based on a Non-Carcinogenic Endpoint

Several agencies have established air quality guidelines based on non-carcinogenic effects. The USEPA (1995) has calculated a Reference Concentration (RfC) of 800 $\mu g/m^3$ for exposure by inhalation on the assumption that there is no difference in toxicity based on the route of exposure. The USEPA used observations of non-carcinogenic effects, primarily liver damage in Sprague-Dawley rats, in a two-generation reproductive study. They used factors for extrapolation

Table 1. Summary of Existing Air Quality Guidelines[1] for 1,4-Dichlorobenzene

Agency, Date[2]	Guideline(s)		Comments
USEPA (IRIS) 1994	no ambient air exposure limits available		
	800 µg/m^3	(reference concentration)	Reference Concentration for evaluating non-cancer risk only
California 1992	700.0 µg/m^3	(inhalation reference exposure level)	Inhalation reference exposure for evaluation of non-cancer risk
	0.91 µg/m^3 0.091 µg/m^3	(lifetime exposure) (lifetime exposure)	$1*10^{-5}$ additional cancer risk $1*10^{-6}$ additional cancer risk Both are based on unit risk of 0.000011 tumours/(µg/m^3)
WHO 1987	None		
Netherlands 1987	0.5 µg/m^3	(maximum emission concentration)	Based on risk assessment in Dutch
Sweden	None		
New York 1990	None		
Massachusetts 1990	122.61 µg/m^3	(24-hour ceiling limit)	24-hour average based on occupational exposure limits
	0.18 µg/m^3	(allowable ambient limit)	$1*10^{-6}$ additional cancer risk Based on a unit risk of 0.0000061 tumours/(µg/m^3)
CEPA 1996	95 µg/m^3	Tolerable Concentration	continuous exposure over a lifetime without deleterious effects
Ontario	None[3]		

1. Guidelines in this table can refer to: guidelines, risk-specific concentrations based on cancer potencies, and non-cancer-based reference concentrations.
2. Date here refers to when the health-based guideline background report or original legislative initiative was issued. Sources were the respective agency documents.
3. Under the Canada - Ontario Agreement (COA), 1,4-dichlorobenzene is listed as a Tier 2 substance. Canada and Ontario agree to collaborate with, and provide support for, voluntary programs by industry and others to reduce the use, release or generation of Tier 2 substances.

from animal to human evidence that took into consideration other relevant laboratory studies. California reports an inhalation REL (chronic reference exposure level) of 700 µg/m^3; however, there is no currently available documentation of their methods of calculation.

Recently, a Tolerable Concentration (TC) was developed under the Canadian Environmental Protection Act - CEPA (Health Canada, 1996). The TC value is derived from a NOEL based on increased liver and kidney weights, urinary protein and coproporphyrin observed at higher concentrations in rats in long-term inhalation study. This route of exposure (ie. inhalation) is most relevant for the general population. The final TC was derived by correcting from discontinuous exposures to continuous exposures and by the application of a number of uncertainty factors to account for intra- and inter- species variation and for the less-than-lifetime exposure of this study. When converted to a daily averaged air concentration, based on an assumed body weight of 27 kg and a respiration rate of 12 m^3/day (for a human aged 5 to 11 years), the TC becomes 95 µg/m^3.

3.2 Recommendations for Ambient Air Quality Standards for 1,4-Dichlorobenzene

Recommendations for new or revised Ontario Ambient Air Quality Criteria (AAQC) and Point of Impingement (POI) standards are based upon a weight-of-evidence evaluation of available information. Information for guidelines, based on cancer and non-cancer endpoints, from various agencies were reviewed, allowing the final guideline recommendation to be made by MOE staff.

The physiological response to 1,4-dichlorobenzene is primarily injury to the liver, and secondarily, injury to the kidney. Epidemiological evidence of human carcinogenicity is considered to be inadequate. Attribution of carcinogenicity to 1,4-dichlorobenzene based on animal studies also appears to be limited.

The California Department of Health Services (CDHS) and the Massachusetts Department of Environmental Protection (MDEP) have based guidelines for 1,4-dichlorobenzene on carcinogenicity. However, supporting documentation for the CDHS guideline was not available and the MDEP guideline was based on an oral (ie. gavage) study. The US EPA has withdrawn its carcinogenicity classification for 1,4-dichlorobenzene pending review of available data. Based on the same NTP data, Health Canada has classified 1,4-dichlorobenzene as a Group III carcinogen (possibly carcinogenic to humans) (CEPA, 1993). In establishing a Tolerable Concentration (TC) for 1,4-dichlorobenzene, Health Canada relied on a no-observed-effect-level (NOEL) from a long-term inhalation study which reported increases in liver and kidney weights, urinary protein and coproporphyrin (CEPA, 1993). An additional uncertainty factor was applied to this value, to account for intra- and inter-species variation and the less-than-lifetime duration of the study. The approach taken by CEPA which post-dates that used in the states of California and Massachusetts is the most recent evaluation of the available toxicity data and is in general agreement with other agencies (IARC, US EPA).

Of the criteria reviewed from other agencies, the Tolerable Concentration developed under the CEPA was judged to have the most appropriate rationale (Health Canada, 1996). The TC has been derived on the basis of the results of studies conducted by the route of exposure which is most important for the general population (i.e. inhalation). Therefore, it is recommended that the air concentration of 95 µg/m^3, derived from the CEPA TC value for inhalation exposure, be used in the Province of Ontario for the basis of developing the 24-hour average ambient air quality criterion for 1,4-dichlorobenzene. The AAQC will be used to assess general air quality and to define the potential for causing an adverse effect.

The relationship between air quality guidelines of different averaging times is based on empirically derived factors which are used to relate short-term maxima concentrations to long-term averages. The factors are selected to ensure that if the short-term limit is met (e.g. half-hour POI limit or 24-hour AAQC), air quality guidelines based on longer-term exposure will not be exceeded. The factor typically used to convert from an annual average to a 24-hour maxima is 5 while the factor used convert from a 24-hour average to an half-hour maximum is 3 (MOEE 1994b). Depending on the critical end-point being considered other factors may also be employed. In cases where the effects of a contaminant can occur over short-term exposures, like odours, the 24-hour Ambient Air Quality Criterion and the half-hour point of impingement standard may have the same value. Starting with an 24-hour average AAQC of 95 µg/m^3 for 1,4-dichlorobenzene, the application of a conversion factor of 3 derives a half-hour limit of 285 µg/m^3 (Table 2).

Table 2: Recommended AAQC and POI Guideline for 1,4-dichlorobenzene

AAQC	24-hour Average	95 µg/m^3
POI Guideline	half-hour Average	285 µg/m^3

At this time the Ministry is recommending a Point of Impingement guideline for 1,4-dichlorobenzene which will be used to assess applications for certificates of approval involving emissions of 1,4-dichlorobenzene. Because of the limited number of industrial sources of 1,4-dichlorobenzene in Ontario, the development of a point of impingement standard under Regulation 346 is not warranted at this time.

While an the recommended air quality standards for 1,4-dichlorobenzene are based on the prevention of adverse health effects in the human population, the potential effects of 1,4-dichlorobenzene on other terrestrial biota including plants, soil microbes and herbivores was also examined and found lacking in information. No information is available on the potential phytotoxic effects of 1,4-dichlorobenzene. If future studies indicate that the proposed air standards for 1,4-dichlorobenzene are not protective of other environmental receptors in Ontario, then the basis on which the standard is established may need to be reviewed.

4.0 Status of Stakeholder Consultations

In January 1997, the Ministry initiated limited stakeholder consultation on the initial suite of 14 proposed air standards developed under the Standards Plan. The purpose of these consultations was to seek comments from Ontario sources and other stakeholders on the standards proposed No comments or concerns were identified with respect to the proposed standard for 1,4-dichlorobenzene.

5.0 Recommendations

Based on an assessment of ambient air quality guidelines used in other jurisdictions; the toxicity of this compound and the levels of 1,4-dichlorobenzene measured in Ontario, the Ministry is proposing to establish:

- a 24-hour average Ambient Air Quality Criterion for 1,4-dichlorobenzene of 95 $\mu g/m^3$ (micrograms dichlorobenzene per cubic metre of air);

- a half-hour point of impingement guideline of 285 $\mu g/m^3$. The point of impingement guideline is based on the proposed 24-hour Ambient Air Quality Criterion and will be used to review and assess applications for Certificates of Approval involving emissions of 1,4-dichlorobenzene from new or modified sources.

6.0 References:

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MOEE, 1994b. Rationale for the Development of Soil, Drinking Water and Air Quality Criteria for Lead. Ministry of Environment and Energy, Toronto, Ont.

MOEE, 1996. Three-Year Plan for Standards-Setting. Ontario Ministry of Environment and Energy. Toronto, Ontario.

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Riley, R.A., I.S. Chart, A. Doss, C.W. Gore, D. Patton and T.M. Weight, 1980. Para-dichlorobenzene: Long-term inhalation study in the rat. ICI Report No. CTL/P/447. August, 1980.

USEPA, 1997. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, D.C.

Windsor, 1994. Windsor Air Quality Study: Ambient Air Monitoring Activities. Fall, 1994. Science and Technology Branch, Ontario Ministry of Environment and Energy.

7.0 Appendix: Agency-Specific Reviews of Air Quality Guidelines

7.1 Agency-Specific Summary: Federal Government of the United States

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: U.S. Environmental Protection Agency

3. Guideline Value(s):
No ambient air exposure limits are currently promulgated and no carcinogenicity assessment is currently available. The IRIS database (USEPA, 1995) gives a Reference Concentration (RfC) of 800 $\mu g/m^3$ (0.8 mg/m^3) for non-carcinogenic risk.

4. Application:
IRIS was developed as a source for consistent risk information on chemicals for use in decision-making and regulatory activities. However, values derived and presented in IRIS in and of themselves do not represent guidelines or standards. IRIS contains a summary of current American government regulatory actions under various legislative mandates.

5. Documentation Available:
USEPA, 1995. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, D.C.

Key Reference(s):
Chlorobenzene Producers Association, 1986. Paradichlorobenzene: Two-generation Reproduction Study in Sprague-Dawley Rats. Study 86-81-90605. MRID No. 411088-1, as cited in USEPA, 1995.

NTP (National Toxicology Program), 1987. Toxicology and carcinogenesis studies of 1,4-dichlorobenzene in F344/N rats and B6C3F1 mice (gavage studies). NTP TR 319. NIH Publ. No. 87-2575, as cited in USEPA, 1995.

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6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world and the published scientific literature, were employed in the development of these values. Both the general assessment methodologies and the chemical-specific information found in IRIS undergo extensive scientific and policy reviews, within both the EPA and other science-based, U.S. regulatory agencies.

Information in IRIS is put forward for use after the results of the public review and comments on draft documents/information have been addressed.

7. Status of Guideline:
No guideline exists. The risk estimate discussed is for respiratory exposure from air only.

8. Key Risk Assessment Considerations:
The USEPA established an RfC, using observations made on Sprague-Dawley rats within a two-generation reproductive study (28/sex/group) reported by the Chlorobenzene Producers Association (1986). The adult rats were exposed to 1,4-dichlorobenzene vapour at concentrations of 0, 50, 150 or 450 ppm (0, 301, 902, 2705 mg/m^3) for 10 weeks, 6 h/day, 7 days/week. The NOAEL established from this study was 50 ppm (301 mg/m^3); the critical effect was a significant increase in liver weights of parental males. Assuming a molecular weight of 147.01 at an ambient temperature of 25°C and pressure of 760 mm Hg, the NOAEL was adjusted to 75 mg/m^3 (301 mg/m^3*6 h/day is equivalent to 75 mg/m^3 over a 24-h period). This adjusted NOAEL was divided by an uncertainty factor of 100. This uncertainty factor included a factor of 10 to account for sensitive sub-populations among humans, a factor of 3 to account for interspecies differences (instead of 10 since dosimetry adjustments were applied) and an additional factor of 3, since the NOAEL was based on a subchronic rather than chronic study. A full factor of 10 was also not used for the latter because the LOAEL estimated by a route-to-route extrapolation from a chronic NTP (1987) oral study and an inhalation study by Riley *et al*. (1980) indicated that once liver lesions arose they did not progress in severity over time.

9. Key Risk Management Considerations:
None, since no guideline for ambient air exists

10. Multimedia Considerations of Guidelines:
None are reported

11. Other Relevant Factors:
The USEPA (1996) described their confidence in the study used to make their assessment, the data base from which the study was drawn and their calculation of the RfC as medium. The critical study employed an extensive reproductive protocol, including histopathologic examination of tissues of adults and offspring. There are a number of supporting studies for the developmental and reproductive toxicology data base. Supporting data for chronic exposure were obtained by performing a route-to-route extrapolation from the chronic NTP (1987) study, and reasonably close correlation for the LOAEL was found. This comparison was done in order to justify using the adult liver data (following 10 weeks of exposure) from the Chlorobenzene Producers Association (1986) study. The results of the NTP (1987) study and the Riley *et al*. (1980) study, which were chronic lifetime exposures, essentially indicate a lack of progression of the hepatic lesions. This information in turn supports the use of the Chlorobenzene Producers Association (1986) study as the critical study and obviates to some extent the concern for the lack of chronic

data. This assessment is not presented in any existing USEPA document. The carcinogenicity is under review by the Agency, and no calculations of carcinogenic potency are currently presented.

7.2 Agency-Specific Summary: State of California

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: State of California (Office of Environmental Health Hazard)

3. Guideline Value(s):
The State of California states that the unit risk of $1.1*10^{-5}$ (0.000011) tumours per $\mu g/m^3$ is to be used for evaluation of cancer risks (CAPCOA, 1993). Thus, $1*10^{-5}$ and $1*10^{-6}$ additional cancer risk levels correspond to lifetime exposures to air concentrations of 0.91 $\mu g/m^3$ and 0.091 $\mu g/m^3$ respectively. The Reference Exposure Level of 700 $\mu g/m^3$ is to be used for non-cancer risk assessment.

4. Application:
"The intent of the Committee in developing the guideline was to provide risk assessment procedures for use in the Air Toxics 'Hot Spots' Program." (CAPCOA, 1993). This program is based on a California State law: the Air Toxics 'Hot Spots' Information and Assessment Act of 1987 (Health and Safety Code Section 44360 *et seq*.). The act specifies how local Air Pollution Control Districts determine which facilities in their areas will prepare health risk assessments, how such health risk assessments should be prepared and how the results are to be prioritized. These guidelines were prepared to provide consistent risk assessment methods and report presentation to enable: 1) comparisons between facilities, 2) expeditious review of risk assessments by reviewing agencies, and 3) minimal revisions and resubmittals of risk assessments. The various health-based exposure levels developed for and employed in this program should not be employed outside the framework of the program. That is to say, the State of California does not consider them to be general, independent, legally enforceable, air quality guidelines or limit values at this time.

5. Documentation Available:
CAPCOA, 1993. CAPCOA Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association.

6. Peer Review Process and Public Consultation:
Cancer potency slope factors and acute and chronic reference levels were prepared by the California Office of Environmental Health Hazard Assessment (OEHHA). These, as well as the exposure and health assessments, have undergone public review and comment prior to finalization. Peer-reviewed scientific research data were employed in the development of these values. Under the CAPCOA risk assessment process, each assessment is site-specific, and public notice to all exposed individuals is required when the screening process determines that a significant health risk is associated with emissions from a facility. Public input was obtained in identifying and ranking areas and facilities for risk assessment screening and, according to the documentation, additional input is expected as the process moves forward.

7. Status of Guideline:
Current, but updates are possible, with new California risk assessment guidelines being considered in the California Senate.

8. Key Risk Assessment Considerations:
CAPCOA (1993) references an assessment by the California Health Department, but it is not currently available.

9. Key Risk Management Considerations:
The exposure guidelines were prepared for both non-cancer- and cancer-based endpoints. The cancer-based value is to be used in a screening risk assessment to determine the maximum offsite cancer risk for the exposed human population. The process is not readily comparable to the air quality guideline approach to non-carcinogens. The non-cancer guidelines are based on the most sensitive adverse health effect reported in the scientific literature and are designed to protect the most sensitive individuals in the population.

There are options for addressing the possible economic impacts of controlling 1,4-dichlorobenzene emissions. It appears that the options are under local control and are based on local risk and socioeconomic analyses, as well as public workshops and hearings. The enforcement mechanism is via operating permits. The process is therefore primarily directed towards site-specific evaluations and development of further regulatory tools, rather than being enforceable levels in and of themselves.

10. Multimedia Considerations of Guidelines:
In the exposure modelling process, non-inhalation pathways should be considered for a number of substances (specified in Table III-5 in CAPCOA, 1993). 1,4-dichlorobenzene is one of the substances that require non-inhalation modelling. In the California EPA exposure and health assessments, it was acknowledged that exposure pathways other than air (e.g., water and food) were possible but that, due the lack of quantitative information and the predominance of airborne exposure, other exposure pathways were not considered in the development of the guideline.

11. Other Relevant Factors:
No information

7.3 Agency-Specific Summary: World Health Organization

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: World Health Organization

3. Guideline Value(s):
None

4. Application:
None

5. Documentation Available:
WHO, 1987. Air Quality Guidelines for Europe. WHO Regional Publications, European Series No. 23. World Health Organization, Regional Office for Europe, Copenhagen, Denmark. 426p.

6. Peer Review Process and Public Consultation:
None

7. Status of Guideline:
No information

8. Key Risk Assessment Considerations:
No information

9. Key Risk Management Considerations:
No information

10. Multimedia Considerations of Guidelines:
No information

11. Other Relevant Factors:
The guideline value is applicable to both indoor and outdoor situations.

7.4 Agency-Specific Summary: The Netherlands

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: Netherlands Ministry of Housing, Spatial Planning and the Environment

3. Guideline Value(s):
The maximum emission concentration (MIC) for airborne effluents from point sources is 0.5 $\mu g/m^3$. No target value is given. No maximum acceptable concentration (MAC) is given.

4. Application:
Limit values are non-statutory environmental quality objectives that are considered to be policy guidelines. They should not be exceeded and should be considered as requirements to be met. These effects-oriented guidelines may be used simultaneously with source-oriented emission criteria, although it is the latter that are the primary regulatory mechanism for waste flows from point-sources. If effects-oriented guidelines continue to be exceeded, then existing source-oriented emissions criteria will be lowered to bring ambient levels below the effects-oriented guidelines. A maximum acceptable concentration (MAC) is the maximum acceptable concentration of a gas, vapour, or mist of a substance in a workplace.

5. Documentation Available:
Netherlands MHSPE, 1994. Environmental Quality Objectives in The Netherlands. A review of environmental quality objectives and their policy framework in The Netherlands. Risk Assessment and Environmental Quality Division, Ministry of Housing, Spatial Planning and the Environment, The Hague, The Netherlands. 465 p.

NeR Staff Office, 1992. Netherlands Emission Regulations - Air. Netherlands Emission Regulations Staff Office, Bilthoven, The Netherlands. 81 p. + Appendices.

6. Peer Review Process and Public Consultation:
No specific information on this issue was presented in the available English language documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
No information

9. Key Risk Management Considerations:
National limit values include consideration of environmental, economic and social interests, and technical options. Specific information on such details was not presented in the available documentation.

10. Multimedia Considerations of Guidelines:

Multimedia exposure was not considered in the development of the current air guideline limits; however, intercompartmental criteria which address this problem are being developed. A specific schedule for revisions based on this process has not been announced and 1,4-dichlorobenzene is not on the initial list of chemicals to be considered.

11. Other Relevant Factors:
No information

7.5 Agency-Specific Summary: Swedish Institute of Environmental Medicine

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: According to Dr. K. Victorin of the Swedish Institute of Environmental Medicine (pers. comm.), no official Swedish air quality guidelines have been promulgated by the Swedish Environmental Protection Agency.

3. Guideline Value(s):
None

4. Application:
None

5. Documentation Available:
Victorin, K., 1993. Health effects of urban air pollutants: guideline values and conditions in Sweden. Chemosphere, 27:1691-1706.

6. Peer Review Process and Public Consultation:
No information

7. Status of Guideline:
No information

8. Key Risk Assessment Considerations:
No information

9. Key Risk Management Considerations:
No information

10. Multimedia Considerations of Guidelines:
No information

11. Other Relevant Factors:
No information

7.6 Agency-Specific Summary: New York State

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: New York State

3. Guideline Value(s):
None

4. Application:
None

5. Documentation Available:
NYDEC, 1991. New York State Air Guideline -1. Guidelines for the Control of Toxic Ambient Air Contaminants. Draft. New York State Department of Environmental Conservation, Albany, N.Y. 20 p. + Appendices.

6. Peer Review Process and Public Consultation:
None

7. Status of Guideline:
None

8. Key Risk Assessment Considerations:
No information

9. Key Risk Management Considerations
None

10. Multimedia Considerations of Guidelines:
No information

11. Other Relevant Factors:
No information

7.7 Agency-Specific Summary: State of Massachusetts

1. Name of Chemical: 1,4-dichlorobenzene

2. Agency: Commonwealth of Massachusetts

3. Guideline Value(s):
A 24-hour ceiling limit is 122.61 $\mu g/m^3$, based on the threshold effects exposure limit (TEL). The allowable ambient limit (AAL) is 0.18 $\mu g/m^3$ for an annual (1 year) averaging time and is based on consideration of carcinogenic effects.

4. Application:
". . . the Division of Air Quality Control, which is responsible for implementing the Department's air programs, plans to employ the AALs in the permitting, compliance, and enforcement components of the Commonwealth's air program in general, and the air toxics program in particular." (Commonwealth of Massachusetts, 1990, Vol. 1, pg. ix). The primary goal is to "protect the public health and welfare from any air contaminant causing known or potentially injurious effects." The ambient air levels developed in this process should not be considered legally enforceable, air quality standards since they deal only with health-related matters and contain no consideration of technological, economic or enforcement concerns. Rather, they should be employed as guidelines in the development of subsequent regulatory action which does contain a broad consideration of all relevant concerns.

5. Documentation Available:
Commonwealth of Massachusetts, 1990. The Chemical Health Effects Assessment Methodology and the Method to Derive Allowable Ambient Limits, Volumes I and II. Commonwealth of Massachusetts, Department of Environmental Protection, Boston, MA.

Key Reference(s):
ACGIH, 1986. Documentation Of The Threshold Limit Values for Substances in Workroom Air (5th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world, and the published scientific literature, were employed in the development of these values. Specifically, evidence from the International Agency for Research on Cancer (IARC), the American National Toxicology Program (NTP) and the USEPA was employed. As guidelines, the process used and values generated are not subject to the extensive review and consultation that air quality standards would be subjected to, but external peer reviews were carried out, and public input was solicited through at least two public meetings on the Massachusetts methodology and guideline document (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.).

7. Status of Guideline:
Current. Although guideline values are periodically updated, revisions to the current value for 1,4-dichlorobenzene are not under consideration (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.).

8. Key Risk Assessment Considerations:
The State of Massachusetts has a method for establishing a limit that assumes the compound has a threshold for adverse effects. In the case of 1,4-dichlorobenzene, the 1986 ACGIH occupational limit of 451 mg/m^3 (ACGIH, 1986; reported as 450.6) was divided by several factors that attempt to extrapolate from a worker health-based limit to a public limit that protects children and other sensitive individuals. The uncertainty factor incorporates judgments about the amount of information on the toxicity of the compound, the differences between body sizes and weights between adult males and children, and an assumption about the relative contribution of the compound to the total exposure from air. The total uncertainty factor in the case of 1,4-dichlorobenzene was 3675.4.

The Massachusetts Department of Environmental Protection (DEP) reported that the USEPA considered 1,4-dichlorobenzene to be a probable human carcinogen. DEP calculated a unit risk value, using the NTP (1986) gavage study. They applied a multistage model to the data on rat male renal tubular adenoma or adenocarcinoma, mouse male hepatocellular adenoma or carcinoma, and mouse female hepatocellular adenoma or carcinoma. The mouse male data provided the highest potency index. The potency index from these data of $2.13*10^{-2}$ tumours per mg/kg/day was used to calculate a unit risk in air of $6.1*10^{-6}$ tumours per µg/m^3. DEP reported that they used the formula of $2.13*10^{-2}$ tumours mg/kg/day*20 m^3/day*1 mg. The actual calculation must have been $2.13*10^{-2}$ tumours*1/[(1 mg/kg/day)*70 kg*1/20 m^3/day*1000 µg/mg)].

9. Key Risk Management Considerations:
The primary objective of the process is the protection of public health. The Massachusetts system uses hazard assessment only and does not use the number of exposed individuals as a criterion for regulatory action. Furthermore, the selection of the AAL is based on the most sensitive effect. The USEPA's cancer unit risk values (USEPA, 1995) and the ACGIH occupational TLV values were adopted for regulation development purposes. For carcinogens, a maximum allowable increase in risk associated with exposure to a chemical was set at one per million ($1*10^{-6}$) for a 70-year lifetime.

10. Multimedia Considerations of Guidelines:
A generic allowance was made for contributions from sources other than respiration: "A relative source contribution factor of 20% is also included to account for sources other than air." (Commonwealth of Massachusetts, 1990, pg. viii).

11. Other Relevant Factors.

The calculation of a unit risk value for air, based on a gavage study, assumes that there are no route-specific differences in carcinogenic potency.